Reblozyl®
(luspatercept-aamt)
for injection 25mg • 75mg

Bristol Myers Squibb™
Access Support®
Your patient. Our commitment.

A REFERENCE GUIDE TO

Reimbursement and Coding REBLOZYL®
(luspatercept-aamt)

To view authorized distributors/specialty pharmacies for REBLOZYL, visit BMSAccessSupport.com.

Please see Important Safety Information on pages 19-20 and U.S. Full Prescribing Information.

Indications

REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

REBLOZYL is indicated for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions.

REBLOZYL is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

In adult patients with beta thalassemia, thromboembolic events (TEE) were reported in 8/223 (3.6%) of REBLOZYL-treated patients. TEEs included deep vein thrombosis, pulmonary embolus, portal vein thrombosis, and ischemic stroke. Patients with known risk factors for thromboembolism (splenectomy or concomitant use of hormone replacement therapy) may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients at increased risk of TEE. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly.

Please see Important Safety Information on pages 19-20 and U.S. Full Prescribing Information.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Bristol Myers Squibb is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that oncology offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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National Drug Code (NDC) Information and Storage for REBLOZYL® (luspatercept-aamt)

The NDCs for REBLOZYL, listed below, are often necessary in addition to the appropriate J code when filing a claim for reimbursement.

NDCs for REBLOZYL[1]

REBLOZYL injection 25 mg/vial
25 mg lyophilized powder in a single-dose vial for reconstitution

59572-0711-01

REBLOZYL injection 75 mg/vial
75 mg lyophilized powder in a single-dose vial for reconstitution

59572-0775-01

The red zero (red text) converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

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Storage[1]

Store vials refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in original carton to protect from light. Do not freeze.

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Healthcare Common Procedure Coding System (HCPCS) and Revenue Codes for REBLOZYL® (luspatercept-aamt)

HCPCS codes are used for billing drugs and services to Medicare, Medicaid, and the commercial payer.

Recommended HCPCS Code for REBLOZYL[2]	
HCPCS Code	Description
J0896	Injection, luspatercept-aamt, 0.25 mg

Billing Unit Conversion[3]			
0.25 mg	1 unit	25-mg vial	100 units
		75-mg vial	300 units

Depending on payer preferences for billing and coding, the billing unit conversion for claim submission may vary. Therefore, the provider should confirm preference with the payer prior to submitting.

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

It is important to note that for accurate reimbursement, any quantity of REBLOZYL that is discarded after treatment should be coded with a **JW modifier**. A JW modifier indicates unused drug or biological from a single-use vial in the event that the entire dose/quantity is not administered and the remainder is discarded.[3]

Use the following claim formats when REBLOZYL is administered to patients on an outpatient basis and billed to health plans:

- Physician office: CMS-1500 (paper format) or ASC 837P (electronic format)
- Hospital outpatient: UB-04 (CMS-1450) (paper format) or ASC 837I (electronic format)

All the coding information presented is applicable to outpatient procedures only. Please see pages 10 and 11 for more information.

Revenue Codes[4] that may be used for administration of REBLOZYL (Hospital Use)	
Revenue Code	Description
0636	Drugs requiring detailed coding
0250	Pharmacy
0331	Chemo admin, injected

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

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Current Procedural Terminology (CPT)* Codes for REBLOZYL® (luspatercept-aamt)

CPT codes are used to indicate which medical services and procedures were performed on a patient and/or how a drug or medical supply was administered.

The CPT codes that may be appropriate for administration of REBLOZYL appear in the table below.

Recommended CPT Codes for REBLOZYL[5]	
CPT Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

Please contact the payer or BMS Access Support® for additional coding information regarding REBLOZYL.

*CPT codes and descriptions only are ©2019 by American Medical Association (AMA). All rights reserved. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

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ICD-10-CM Diagnosis Codes

ICD-10-CM diagnosis codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States. This version replaces the previous version, ICD-9-CM.

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM diagnosis codes for the labeled indications for REBLOZYL are provided on page 8 by Bristol Myers Squibb and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**.

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ICD-10-CM Diagnosis Codes for REBLOZYL® (luspatercept-aamt)

ICD-10-CM Diagnosis Codes for Beta Thalassemia[6]	
ICD-10-CM Code	Description
D56.1	Beta thalassemia major and intermediate • Beta thalassemia major • Cooley's anemia • Homozygous beta thalassemia • Severe beta thalassemia • Thalassemia intermedia • Thalassemia major
D56.5	Hemoglobin E-beta thalassemia

ICD-10-CM Diagnosis Codes for MDS Associated Anemia[6]	
ICD-10-CM Code	Description
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified

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5010 Electronic Transaction Coding for REBLOZYL® (luspatercept-aamt)

- For electronic transactions, including 837P and 837I, the 11-digit NDC is to be preceded by the qualifier N4 for payers that require it[7]
- This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter), and the quantity administered[7]

5010 Transaction Coding for REBLOZYL[1,7]

How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
25 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution	59572-0711-01	N4	UN	N459572071101UN100
75 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution	59572-0775-01	N4	UN	N459572077501UN300

The example given in the far-right column demonstrates NDC quantity reporting for 1 vial of REBLOZYL. The actual amount of drug used can vary based on factors such as patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

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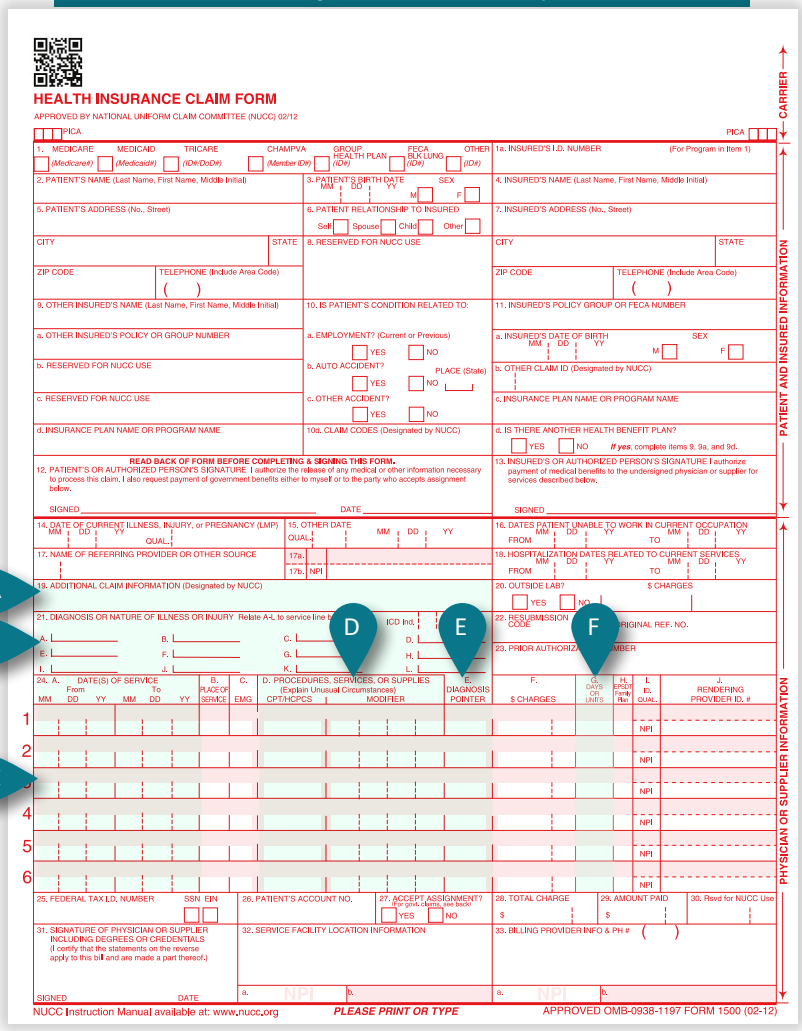
Coding and Billing Units for REBLOZYL® (luspatercept-aamt)

Please contact the payer or BMS Access Support® for additional information on coding and billing units

CMS-1500 Form: Physician Office Sample Claim Form



This sample form is for informational purposes only.

A **Item 19:** Many payers require detailed information about the drug in Box 19.[7] Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

B **Item 21:** Enter the ICD-10-CM code[7]

C **Item 24A:** NDC information is required in the shaded area above the line on which a drug is reported in 24D.[7] The NDC is preceded by the qualifier N4 and followed by the quantity qualifier (UN) and the quantity administered beginning in position 14.[7] For example, use "N459572077501UN300" for one 75-mg vial[1]

D **Item 24D:** Enter the appropriate HCPCS code (J0896) and appropriate CPT code(s)* for drug administration services; include modifiers, if applicable.[2,3,7] In addition, it is required that you enter J0896-JW on next line to record waste

E **Item 24E:** Enter the diagnosis code reference letter or number from Box 21 that relates to the date of service and the services or procedures performed that is entered on that same line under 24D[7]

F **Item 24G:** Billing units are reported here.[7] 0.25 mg = 1 billing unit[3]

A claim for REBLOZYL should include the following[3]:

- A proper HCPCS code to define the drug and billing unit
- The quantity of billing units provided to the patient
- A CPT code that indicates how the physician administered the drug

In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity.

*Any outpatient red blood cell transfusions given to address hemoglobin levels in patients with beta thalassemia or MDS entail their own set of HCPCS and CPT codes.

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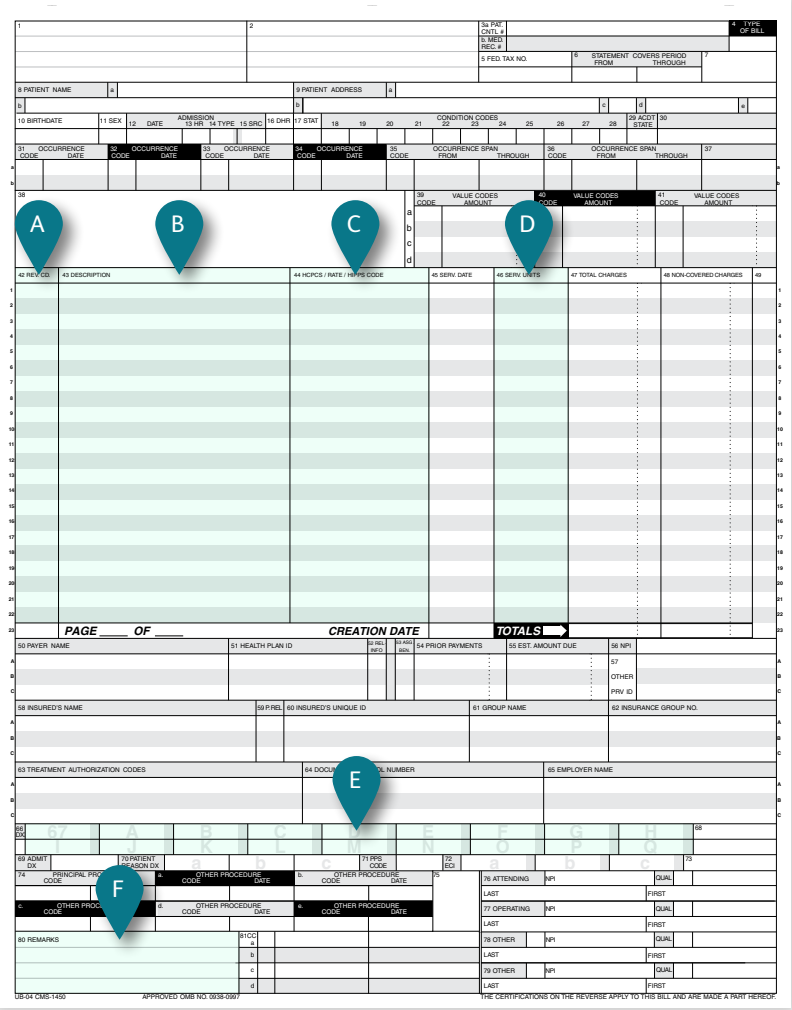
Coding and Billing Units for REBLOZYL® (luspatercept-aamt) (cont'd)

UB-04 Form (CMS-1450): Hospital Outpatient Department Sample Claim Form



A **Form Locator (FL) 42:** Enter a 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.[8] CMS recommends using revenue code 0636 (drugs requiring detailed coding)[3,4]

B **FL 43:** Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.[8] For example, use "N459572077501UN300" for one 75-mg vial [1,8]

C **FL 44:** Enter HCPCS code (J0896) and code for the outpatient service (and modifier[s],* if applicable).[2,3,8] In addition, it is required that you enter J0896-JW on next line to record waste

D **FL 46:** Billing units are called *service units* and are placed here.[8] 0.25 mg = 1 billing unit[3]

E **FLs 67:** Enter the ICD-10-CM diagnosis code[8]

F **FL 80:** Some payers require detailed information about the drug in FL 80.[8] Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

This sample form is for informational purposes only.

UB-04 is used for reimbursement of REBLOZYL administered in an institutional setting, such as a hospital, a clinic, or an ambulatory surgical center.[8] Providers must submit a UB-04 claim form documenting the drug administered and associated services.

*Any outpatient red blood cell transfusions given to address hemoglobin levels in patients with beta thalassemia or MDS entail their own set of HCPCS and CPT codes and revenue codes. Certain level II HCPCS codes and CPT codes require the use of modifiers to improve coding accuracy.

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Dosage and Administration for REBLOZYL® (luspatercept-aamt) In beta thalassemia

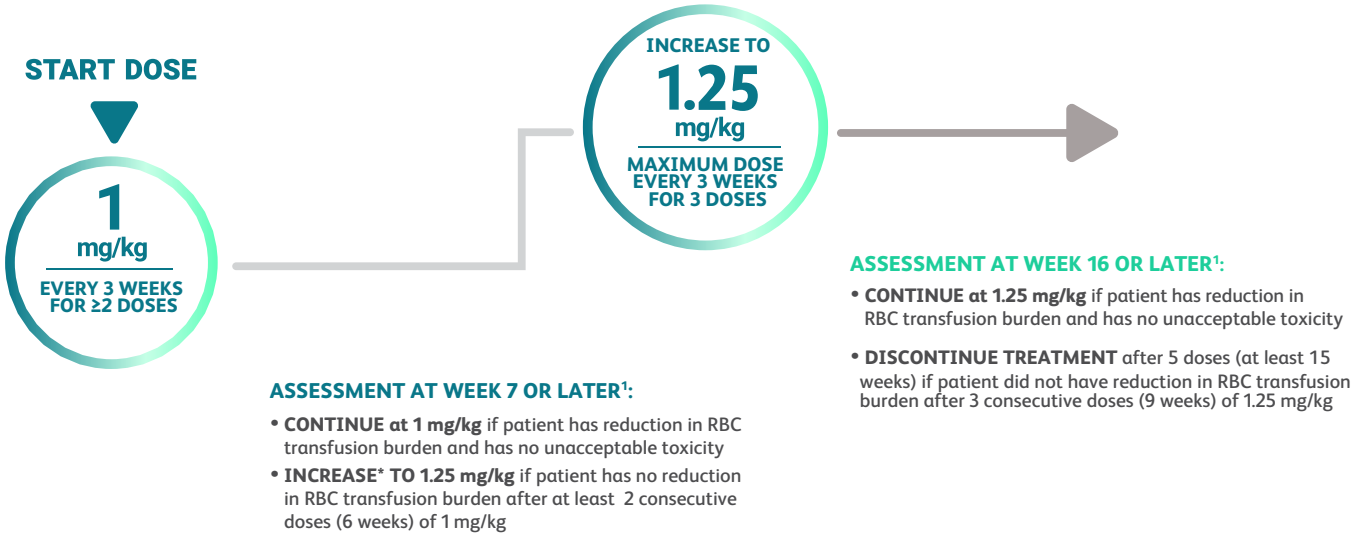
REBLOZYL has 2 dose levels to optimize response in patients with beta thalassemia[1]

Assess and review the patient's Hgb and transfusion record prior to each administration

- If an RBC transfusion occurred prior to dosing, use the pretransfusion Hgb for dose evaluation
- If a patient experiences a dose delay due to Hgb increase, measure Hgb every week[9]

REBLOZYL dose titration for response[1]

- Increase REBLOZYL dose with the goal of achieving reduction in transfusion burden, but do not increase if patient is experiencing adverse reactions. Discontinue REBLOZYL after 3 doses at the maximum dose if no transfusion burden reduction or if unacceptable toxicity occurs



Treat for at least 15 weeks (5 doses) unless unacceptable toxicity occurs at any time

*Do not increase the dose if the patient is experiencing an adverse reaction as described in the Dose Modifications for Adverse Reactions table.[1]

Hgb=hemoglobin; RBC=red blood cell.

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Dosage and Administration for REBLOZYL® (luspatercept-aamt) In beta thalassemia (cont'd)

Modifications for predose Hgb levels or rapid Hgb rise[1]

SCENARIO	REBLOZYL Dosing recommendation
Predose Hgb is **≥11.5 g/dL** in the absence of transfusions	• Interrupt treatment • Restart when the Hgb is no more than **11 g/dL**
Increase in Hgb >2 g/dL within 3 weeks in the absence of transfusions and:	
Current dose is **1.25 mg/kg**	• Reduce dose to **1 mg/kg**
Current dose is **1 mg/kg**	• Reduce dose to **0.8 mg/kg**
Current dose is **0.8 mg/kg**	• Reduce dose to **0.6 mg/kg**
Current dose is **0.6 mg/kg**	• Discontinue treatment

Hgb=hemoglobin.

Dose increase in the event of loss of response[1]

- A dose increase to 1.25 mg/kg may occur at any time during treatment after patients have received at least 2 consecutive doses of 1 mg/kg
- **Do not increase the dose beyond the maximum dose of 1.25 mg/kg**

Discontinue treatment if no reduction in transfusion burden is observed[1]

- Discontinue REBLOZYL if a patient does not experience a decrease in transfusion burden after 3 doses (9 weeks of treatment) at the maximum dose level or if unacceptable toxicity occurs at any time

If a planned administration of REBLOZYL is delayed or missed[1]

- Administer REBLOZYL as soon as possible and continue dosing as prescribed, with at least 3 weeks between doses

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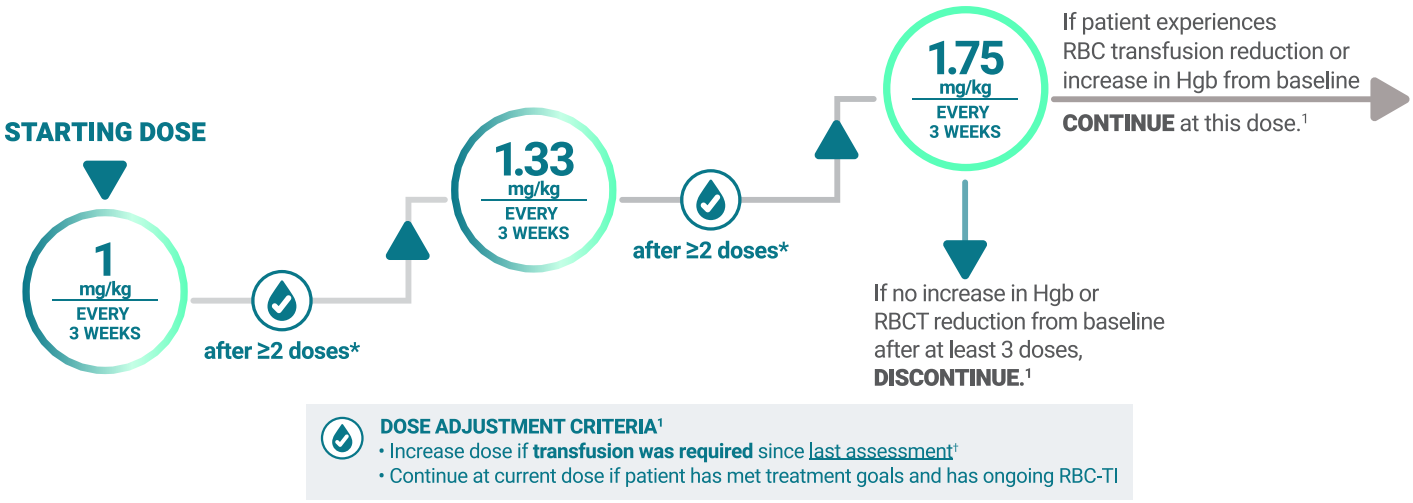
Dosage and Administration for REBLOZYL® (luspatercept-aamt) In MDS associated anemia

Recommended dosing for REBLOZYL[1]

Expect to escalate dose to meet patient treatment goals[1]

- Prior to each REBLOZYL administration, assess if patient may require a dose adjustment. Review Hgb prior to administration. If RBC transfusion occurred, use pretransfusion Hgb since last dose
- Following at least 2 doses at the same level, dosing adjustments can be considered at any time during therapy
- **Do not continue treatment or increase dose if patient is experiencing unacceptable toxicity or an adverse event**



*Do not increase dose more frequently than every 6 weeks (2 doses); do not increase dose beyond maximum dose.
†In the absence of transfusion, if predose Hgb is ≥11.5 g/dL or if Hgb increases >2g/dL within 3 weeks, interrupt or decrease dose. See instructions for dosing modifications.

Hgb=hemoglobin; RBC=red blood cell; RBCT=red blood cell-transfusions; RBC-TI=red blood cell transfusion independence.

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Dosage and Administration for REBLOZYL® (luspatercept-aamt) In MDS associated anemia (cont'd)

Dose modifications when administering REBLOZYL

SCENARIO	REBLOZYL Dosing recommendation
Predose Hgb is **≥11.5 g/dL** in the absence of transfusions	• Interrupt treatment • Restart when the Hgb is no more than **11 g/dL**
Increase in Hgb >2 g/dL within 3 weeks in the absence of transfusions and:	
Current dose is **1.75 mg/kg**	• Reduce dose to **1.33 mg/kg**
Current dose is **1.33 mg/kg**	• Reduce dose to **1 mg/kg**
Current dose is **1 mg/kg**	• Reduce dose to **0.8 mg/kg**
Current dose is **0.8 mg/kg**	• Reduce dose to **0.6 mg/kg**
Current dose is **0.6 mg/kg**	• Discontinue treatment

Hgb=hemoglobin.

Dose increase in the event of loss of response[1]

- If, upon dose reduction, the patient loses response (ie, requires a transfusion) or Hgb concentration drops by 1 g/dL or more in 3 weeks in the absence of transfusion, increase the dose by 1 dose level
- Wait a minimum of 6 weeks between dose increases
- Dose increases to 1.33 mg/kg and subsequently to 1.75 mg/kg may occur at any time during treatment after patients have received at least 2 consecutive doses at the prior lower dose level
- Do not increase the dose more frequently than every 2 consecutive doses (6 weeks) or beyond the maximum dose of 1.75 mg/kg

Discontinue treatment if no clinical benefit is observed

- Discontinue REBLOZYL if no increase in Hgb or reduction in RBC transfusion burden from baseline after at least 3 consecutive doses (9 weeks) at 1.75 mg/kg or if unacceptable toxicity occurs at any time

If a planned administration of REBLOZYL is delayed or missed[1]

- Administer REBLOZYL as soon as possible and continue dosing as prescribed, with at least 3 weeks between doses

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Dosage and Administration for REBLOZYL® (luspatercept-aamt) (cont'd)

Dose modifications for adverse reactions

SCENARIO	REBLOZYL Dosing recommendation[a]
Grade 3 or 4 hypersensitivity reactions	• Discontinue treatment
Other Grade 3 or 4 adverse reactions	• Interrupt treatment • **Beta thalassemia:** restart when the adverse reaction resolves to no more than Grade 1 • **MDS associated anemia:** – when the adverse reaction resolves to no more than Grade 1, restart treatment at the next lower dose level[b] – If the dose delay is >12 consecutive weeks, discontinue treatment
Extramedullary hematopoietic (EMH) masses causing serious complications	**Beta thalassemia:** discontinue treatment

[a]Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.
[b]Per dose reductions in MDS dose titration for response table on page 14.

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Medicare Drug Reimbursement for REBLOZYL® (luspatercept-aamt)

Coverage of REBLOZYL by Medicare is expected to follow guidance within chapter 15 of the *Medicare Benefit Policy Manual*, which states that "the program covers drugs that are furnished 'incident to' a physician's service provided that the drugs are not usually self-administered by the patients who take them."[10] An injectable drug or biologic is typically eligible for inclusion under the "incident to" benefit when it is FDA approved, in a form not usually self-administered, furnished by a physician, and administered by the physician or by auxiliary personnel employed by the physician and under the physician's personal supervision.[10] It also can be furnished by other healthcare professionals.[10] In addition, the drug must also be reasonable and necessary for an individual patient, as well as safe and effective.[10]

What is the Medicare reimbursement allowable for REBLOZYL?

Physicians*

- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents 1 billing unit of REBLOZYL, which is billed for each 0.25 mg[3,11†]
- The amount paid to providers is published at the beginning of each calendar quarter in "Payment Allowance Limits for Medicare Part B Drugs,"[11] which can be downloaded at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2023-asp-drug-pricing-files
- Medicare Part B will pay physicians 80% of the allowed price for REBLOZYL; the patient is responsible for 20% coinsurance, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc)[12]

Hospital outpatient facilities*

Drugs paid separately in the hospital outpatient setting are based on 106% of average sales price (ASP), not including sequestration, for 1 billing unit for the corresponding HCPCS code. This is 0.25 mg for REBLOZYL.[3,11†]

- The Payment Allowance Limits[11] are published each quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs[13,14]
- This prospective rate does not allow for drugs to be paid separately[15]

* While the statutory amount that Medicare will reimburse for a Part B drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[16]

† See the Centers for Medicare & Medicaid Services' (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

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Commercial Insurance Reimbursement for REBLOZYL® (luspatercept-aamt)

Physicians

- Drug reimbursement, like service reimbursement, is usually based on a fee schedule[17]
- The fee schedules are based on the ASP or AWP, as published by a credible source,[18,19] or an average costing methodology as determined by the payer, such as usual, customary, and reasonable (UC&R)[20]

Hospital outpatient facilities

- In this setting, reimbursement is most commonly based on percentage of charges[19]
- Alternatively, some hospitals use the same ASP or AWP methodologies typically used by physician offices[19]
- Other methodologies include capitated model, cost minus submitted charges, or discount off submitted charges[19]

Hospital inpatient settings

- Inpatient rates are prospective, meaning they are predetermined per discharge[13,14]
- There are private payers that pay on a version of the DRGs[14]
- There are also payers that pay on a negotiated and fixed rate per day called a "per diem."[14] There are capitated rates for inpatients as well[14]
- New drugs may be carved out of per diems or capitated rates, if the hospital negotiates to do so[21]

Medicaid Insurance Reimbursement for REBLOZYL

Medicaid is a joint federal-state program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Medicaid programs are established and administered by each individual state.[20] Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs.[19] Benefits for Medicaid patients should be verified to identify additional needs, such as prior authorizations.

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Important Safety Information for REBLOZYL® (luspatercept-aamt)

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

In adult patients with beta thalassemia, thromboembolic events (TEE) were reported in 8/223 (3.6%) of REBLOZYL-treated patients. TEEs included deep vein thrombosis, pulmonary embolus, portal vein thrombosis, and ischemic stroke. Patients with known risk factors for thromboembolism (splenectomy or concomitant use of hormone replacement therapy) may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients at increased risk of TEE. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly.

Hypertension

Hypertension was reported in 11.4% (63/554) of REBLOZYL-treated patients. Across clinical studies, the incidence of Grade 3 to 4 hypertension ranged from 2% to 9.6%. In patients with beta thalassemia with normal baseline blood pressure, 13 (6.2%) patients developed systolic blood pressure (SBP) ≥130 mm Hg and 33 (16.6%) patients developed diastolic blood pressure (DBP) ≥80 mm Hg. In ESA-refractory or -intolerant adult patients with MDS with normal baseline blood pressure, 26 (30%) patients developed SBP ≥130 mm Hg and 23 (16%) patients developed DBP ≥80 mm Hg. In ESA-naïve adult patients with MDS with normal baseline blood pressure, 23 (36%) patients developed SBP ≥140 mm Hg and 11 (6%) patients developed DBP ≥80 mm Hg. Monitor blood pressure prior to each administration. Manage new or exacerbations of preexisting hypertension using anti-hypertensive agents.

Extramedullary Hematopoietic Masses

In adult patients with transfusion-dependent beta thalassemia, EMH masses were observed in 3.2% of REBLOZYL-treated patients, with spinal cord compression symptoms due to EMH masses occurring in 1.9% of patients (BELIEVE and REBLOZYL long-term follow-up study).

In a study of adult patients with non-transfusion-dependent beta thalassemia, a higher incidence of EMH masses was observed in 6.3% of REBLOZYL-treated patients vs. 2% of placebo-treated patients in the double-blind phase of the study, with spinal cord compression due to EMH masses occurring in 1 patient with a prior history of EMH. REBLOZYL is not indicated for use in patients with non-transfusion-dependent beta thalassemia.

Possible risk factors for the development of EMH masses in patients with beta thalassemia include history of EMH masses, splenectomy, splenomegaly, hepatomegaly, or low baseline hemoglobin (<8.5 g/dL). Signs and symptoms may vary depending on the anatomical location. Monitor patients with beta thalassemia at initiation and during treatment for symptoms and signs or complications resulting from the EMH masses and treat according to clinical guidelines. Discontinue treatment with REBLOZYL in case of serious complications due to EMH masses. Avoid use of REBLOZYL in patients requiring treatment to control the growth of EMH masses.

Embryo-Fetal Toxicity

REBLOZYL may cause fetal harm when administered to a pregnant woman. REBLOZYL caused increased post-implantation loss, decreased litter size, and an increased incidence of skeletal variations in pregnant rat and rabbit studies. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the final dose.

Please see U.S. Full Prescribing Information for REBLOZYL.

Please see Important Safety Information on pages 19-20 and U.S. Full Prescribing Information.

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Important Safety Information for REBLOZYL® (luspatercept-aamt) (cont'd)

ADVERSE REACTIONS

Beta-Thalassemia

Serious adverse reactions occurred in 3.6% of patients on REBLOZYL. Serious adverse reactions occurring in 1% of patients included cerebrovascular accident and deep vein thrombosis. A fatal adverse reaction occurred in 1 patient treated with REBLOZYL who died due to an unconfirmed case of acute myeloid leukemia (AML).

Most common adverse reactions (at least 10% for REBLOZYL and 1% more than placebo) were headache (26% vs 24%), bone pain (20% vs 8%), arthralgia (19% vs 12%), fatigue (14% vs 13%), cough (14% vs 11%), abdominal pain (14% vs 12%), diarrhea (12% vs 10%) and dizziness (11% vs 5%).

ESA-naïve adult patients with Myelodysplastic Syndromes

Grade ≥3 (≥2%) adverse reactions included hypertension and dyspnea.

The most common (≥10%) all-grade adverse reactions included diarrhea, fatigue, hypertension, peripheral edema, nausea, and dyspnea.

ESA-refractory or -intolerant adult patients with Myelodysplastic Syndromes

Grade ≥3 (≥2%) adverse reactions included fatigue, hypertension, syncope and musculoskeletal pain. A fatal adverse reaction occurred in 5 (2.1%) patients.

The most common (≥10%) adverse reactions included fatigue, musculoskeletal pain, dizziness, diarrhea, nausea, hypersensitivity reactions, hypertension, headache, upper respiratory tract infection, bronchitis, and urinary tract infection.

LACTATION

It is not known whether REBLOZYL is excreted into human milk or absorbed systemically after ingestion by a nursing infant. REBLOZYL was detected in milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because many drugs are excreted in human milk, and because of the unknown effects of REBLOZYL in infants, a decision should be made whether to discontinue nursing or to discontinue treatment. Because of the potential for serious adverse reactions in the breastfed child, breastfeeding is not recommended during treatment and for 3 months after the last dose.

DRUG ABUSE POTENTIAL

Abuse: Abuse of REBLOZYL may be seen in athletes for the effects on erythropoiesis. Misuse of drugs that increase erythropoiesis, such as REBLOZYL, by healthy persons may lead to polycythemia, which may be associated with life-threatening cardiovascular complications.

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References

1. REBLOZYL [package insert]. Summit, NJ: Celgene Corp.
2. Centers for Medicare & Medicaid Services. First Quarter, 2020 Coding Cycle for Drug and Biological Products. Updated April 14, 2020. Accessed June 28, 2023. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-1-2020-drugs-and-biologicals-updated-04142020.pdf.
3. Medicare Claims Processing Manual. Chapter 17 – Drugs and Biologicals Revision 11572, August 25, 2022. Accessed June 28, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.
4. National Uniform Billing Committee (NUBC). Official UB-04 Data Specifications Manual 2021. American Hospital Association; 2020.
5. American Medical Association. CPT Professional 2023. American Medical Association; 2022.
6. Centers for Medicare & Medicaid Services. 2023 ICD-10-CM tabular list of diseases and injuries. April 1, 2023. Accessed June 28, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm.
7. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Revision 11037, May 27, 2022. Accessed June 18, 2023. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf.
8. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25 – Completing and Processing the Form CMS-1450 Data Set. Revision 10880, August 6, 2021. Accessed July 21, 2023. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf.
9. Data on file. Celgene Corporation. Summit, New Jersey.
10. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. Revision 11865, February 16, 2023. Accessed July 21, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.
11. Centers for Medicare & Medicaid Services. July 2023 ASP drug pricing files. Updated July 6, 2023. Accessed July 17, 2023. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2023-asp-drug-pricing-files.
12. Centers for Medicare & Medicaid Services. Your Medicare Benefits. CMS product number 10116. Revised January 2021. Accessed April 25, 2021. https://www.medicare.gov/Pubs/pdf/10116-Your-Medicare-Benefits.pdf.
13. Centers for Medicare & Medicaid Services. Acute inpatient PPS. Updated June 12, 2023. Accessed July 21, 2023. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index?redirect=/acuteinpatientpps.
14. Academy of Managed Care Pharmacy. AMCP guide to pharmaceutical payment methods, executive edition, version 3.0; 2013. Revised April 2013. Accessed July 21, 2023. https://www.amcp.org/sites/default/files/2019-03/MM%20edits-Executive_Summary%20%28final-mar27%29_MB.pdf.
15. Centers for Medicare & Medicaid Services. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates. Federal Register. 87 FR 48780. August 10, 2022. Accessed July 20, 2023. https://www.federalregister.gov/d/2022-16472.
16. Mandatory payment reductions in the Medicare Fee-for-Service (FFS) program—"sequestration." News release. Medical Learning Network, Centers for Medicare & Medicaid Services CMS Medicare FFS Provider e-News; March 8, 2013. Accessed July 21, 2023. https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf.
17. Robinson JC. Insurers' strategies for managing the use and cost of biopharmaceuticals. Health Aff (Millwood). 2006;25(5):1205-1217.
18. American Society of Clinical Oncology. Payment reform glossary. ASCO website. Accessed July 21, 2023. https://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/pdf/Payment-Reform-Glossary.pdf.
19. Magellan Rx Management. Medical Pharmacy Trend Report 2016. http://www.magellanrxinsights.com.
20. US Bureau of Labor Statistics. Definitions of health insurance terms. http://www.bls.gov/ncs/ebs/sp/healthterms.pdf.
21. Academy of Managed Care Pharmacy. Managed care glossary. Accessed July 21, 2023. https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary.

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